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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,845	01/13/2006	Gael Lamoureux	TIP-0047-USPCT	2346

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	PAPER NUMBER
4161	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,845	LAMOUREUX ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-17 are currently pending.

Election/Restrictions

Applicants' election of group II drawn to a particle composition, in the reply filed on 9/15/2008 is acknowledged.

The election was made with traverse on the ground that a search and examination of the claims in Groups I and II would not place an undue burden on the office. This is not found to be persuasive because search burden being undue is a moot argument for lack of unity issue. The requirement is still deemed proper and is therefore made final.

Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Claims 10- and 17 are under examination in the instant office action.

Priority

The instant application is a 371 of PCT/EP04/51545 filed on 7/19/2004 and claims benefit of foreign applications filed on 7/02/2004 and 7/17/2003. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Certified copies of foreign applications have been submitted on 1/13/2006.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 7/19/2004.

Information Disclosure Statement

A signed and initialed copy of the information disclosure statement filed on 1/13/2006 is enclosed in this action.

Claim objections

Claim 11 is objected because it depends from non-elected claim.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in this rejection.

Claims 10 recites "at least one antiviral pyrimidine and triazine", however it is unclear whether this means at least one antiviral agent selected from antiviral pyrimidine or antiviral triazine, or at least one antiviral agent from each of antiviral pyrimidine and antiviral triazine, thus it renders the claim indefinite. Claims 11-17 are rejected because they depend from claim 10; thus incorporate its limitation.

For the examination purpose, it is interpreted as at least one antiviral agent selected from antiviral pyrimidine or antiviral triazine in the further action, based on the instant specification (p22, lines 27-37)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 0027825 (pub date: 5/18/2000). WO 00/27825 was supplied by Applicant on the IDS received on 1/13/2006.

The instant invention is drawn to a particle comprising a co-precipitate applied in a layer surrounding a neutral hydrophilic carrier, and comprising at least one antiviral pyrimidine or triazine, at least one surface-active agent, and at least one hydrophilic polymer.

WO 00/27825 teaches a pharmaceutical composition comprising a solid dispersion (which is obtaind via evaporation of a solution consisiting of the active ingredient and an inert polymeric material and thus is considered as co-precipitate) of a pyrimidine derivative having HIV inhibiting property with a surface modifier (equivalent to surface active agent) and preferably, in a mixture with hydrophilic polymers as a coat film on cores such as saccharide beads (a neutral hydrophilic carrier) (p18, line 35-p19, line 8 and p20, line 24-p21, line 3). The

reference further teaches that the particle can then be formulated by conventional techniques in to pharmacological dosage forms such as tablets and capsules (p18, lines 29-34).

As such, claims 10 and 17 are anticipated by WO 00/27825.

Claim Rejections - 35 USC § 102/103

Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 00/27825 A1.

As stated in the above 102 rejection, WO 00/27825 teaches the same product comprising the same ingredients, made by the almost identical process although the reference is silent about how many times the solution comprising a therapeutic agent and a hydrophilic polymer is sprayed on the inert carrier and whether each of these steps is followed by a grinding step as recited in the instant claim 1. Also, the applicant has not shown the superior properties of the obtained particles resulting from this special process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process, either 102 or 103 rejection can be properly made. See *In re Marosi*, 710 F.2d 799, 218

USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP §2113.

Thus, claim 11 is anticipated by or, in the alternative, obvious over WO 0027825 A1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,027,747 (Issue date: 2/22/2000) in view of WO 01/22938 A1 (pub. Date: 4/5/2001). A copy of WO 0122938 A1 is not supplied because it is cited in the instant specification thus Applicants have a copy.

US 6,027,747 teaches a solid dispersion of at least one therapeutic agent preferably hardly water-soluble active ingredients such as antivirals in a hydrophilic carrier, made by the

process comprising dissolving at least one therapeutic agent in a volatile organic solvent containing a very hydrophilic polymer and evaporating the solvent to dryness to form a co-precipitate of therapeutic agent and hydrophilic polymer (abstract and column 3, line 49-column 4, line 8) and this process provide a novel process for dry pharmaceutical products and the co-precipitate formed thereby which has faster and greater resorption when administered orally (column 2, lines 17-20). It further teaches that a surface-active agent such as non-ionic surface agent can be further added (column 3, lines 33-38). In the preferable examples, the amount of surface agent ranges from 0.5 to 20%, preferably 1-10% , related to the whole mass, which overlaps or falls within the claimed ranges in instant claims 12 and 15, and the weight ratio of the hydrophilic polymer (polyvinyl pyrrolidone) to the active ingredient (progesterone) ranges about 4:1 to 1:1 (column 5, lines 47-50 and tables I-III), which falls within the claimed range in the instant claim 14. US 6,027,747 teaches that for a pharmaceutical dosage form, the granules or the pellets are made of any carbohydrates (neutral hydrophilic carrier) such as starch, saccharose dextrins or cellulose and the organic solution comprising a therapeutic agent and a hydrophilic polymer is sprayed thereon (column 6, lines 41-43). Furthermore, it teaches that the particle size of the samples for the galenical tests is lower than 100 μm (column 17, lines 65-67). Although the reference is silent about how many times the solution comprising a therapeutic agent and a hydrophilic polymer is sprayed on the inert carrier and whether each of these steps is followed by a grinding step as recited in the instant claim 1. The product by process set forth in the instant claim 11 is obvious from a product of the prior art unless the applicant shows the superior properties of the obtained particles resulting from this special process as stated in the above 102/103 rejection.

The reference differs from the instant invention insofar as it does not expressly teach specific species of antiviral agents such as antiviral pyrimidine or triazine. Also, it is silent about the inert hydrophilic carrier being present in an amount of up to 95% by weight.

WO 01/22938 A1 teaches a pharmaceutical composition containing an antiviral pyrimidine or a triazine compound, or their combination and one or more water-soluble (hydrophilic) polymers (abstract and p33, line 35-p34, line 3). It further teaches the pharmaceutical composition can be prepared as a solid dispersion by various techniques such as melt-extrusion, spray-drying and solution-evaporation, melt-extrusion being preferred (p37, lines 34-37) and the solid dispersion products is milled or ground to particles having a particle size of less than 1500 μm, preferably less than 400 μm, more preferably less than 250 μm and most preferably less than 125 μm (p39, lines 17-19).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made to use any of the species of the genus of antiviral agents for making a particle as taught by US 6,027,747 because any such antiviral agent could have been used, including antiviral pyrimidine or triazine and furthermore, WO 01/22938 A1 teaches antiviral pyrimidine or triazine compound or its combination, which can be prepared as a particle of a solid dispersion.

In addition, one of ordinary skill in the art at the time of the invention was made would have reasoned that the inert hydrophilic carrier can not be present more than 95% by weight since the particle should also contain the other ingredients including a therapeutic agent, a hydrophilic polymer, and a surface-active agent.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-17 of copending Application No. 10/564786. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application 10/564786 are anticipated by the instant claims. The instant claims are drawn a particle composition comprising a specific active substance such as antiviral pyrimidine or triazine while those of the copending application 10/564786 are drawn to the same particle composition containing any active substance. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slater*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gustily*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gustily claimed a genus of 21 specific chemical species of bicyclical thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BONG-SOOK BAEK
Examiner, Art Unit 4161

Bbs

/Patrick J. Nolan/

Supervisory Patent Examiner, Art Unit 4161